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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,252	07/25/2001	Ed Croze	BERLX-79	4123
23599	7590	01/18/2005	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			NGUYEN, QUANG	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/912,252

Applicant(s)

CROZE ET AL.

Examiner

Quang Nguyen, Ph.D.

Art Unit

1636

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 22 December 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1,3,4,6-14 and 22-24.

Claim(s) withdrawn from consideration: 5 and 15-21.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
DAVID GUZO  
PRIMARY EXAMINER

Continuation of 2. NOTE: The proposed amendment contains 3 additional new claims 25-27, and with respect to the new claim 27 which is drawn to a method of treating a patient suffering from a proliferative cell condition, it would raise new issues that would require further consideration and/or search. Additionally, proposed claim 22 recites "said cells of said target cell population in culture" would raise a new ground of rejection, USC 112, second paragraph for the lack of antecedent basis. Furthermore, non-elected claims have not been cancelled in response to the final rejection (see 37 CFR 1.144).

Continuation of 5. does NOT place the application in condition for allowance because: the proposed amendment has not been entered for the reasons already set forth above.

1. With respect to Applicant's request for withdrawal of Finality of the Office Action, Applicants argue basically that the limitation added in new claim 23 would have been reasonably expected, given the examples present in the specification, and therefore the second action should not be made final as being anticipated by Lutfalla et al. Additionally, Applicants argue that the rejection of claims 1, 3-4, 6 or 11-12 was not necessitated by the amendment made by the Applicants in their response filed June 14, 2004.

Please note that new claim 23 specifically recites the new limitation "wherein said cells are human and said IFNAR2c is human", and claim 23 is dependent on claim 1. This new limitation necessitates a new ground of rejection based on the teachings of Lutfalla et al. It is also apparent that an embodiment of claim 1 and its dependent claims also contain this new limitation. Furthermore, it should be noted that it is improper for the Examiner to read the specification into the claims, and it is also unreasonable for the examiner to guess which limitation(s) Applicants will or will not recite in the claims. Accordingly, the finality of the last office action is proper and it is maintained.

2. With respect to 35 USC 112, first paragraph, it is noted that Applicants' arguments are not directed to the breadth of the claims encompassing any route of delivery (administering directly as well as a systemic delivery of an exogenous gene encoding IFNAR2c into cells of a target cell population) as already noted in last office action (pages 2-3).

3. With respect to the rejection under 35 USC 102(b) as being anticipated by Domanski et al., Applicants argue that the data from Platanius et al demonstrate that while human IFNalpha2 and IFNbeta produce an antiviral response in these cells, the cells do not respond to the antiproliferative effects of human type I IFNs (see abstract), and therefore the method taught by Domanski et al. does not result in antiproliferative effects.

Please note that the abstract of Platanius et al. also states "these cells respond to the antiproliferative effects of murine IFNalphabeta" (see abstract), and it is further noted that the majority of the claims do not limit to human type IFNs.

4. With respect to the rejection under 35 USC 102(b) as being anticipated by Lutfalla et al., Applicants argue that Lufalla et al do not teach or suggest that increasing the number of IFNAR2-c receptors on the surface of cells would provide a method for inhibiting cell proliferation.

Please note that the instant claims do not exclude cells that are defective in IFNalphabeta binding, and that the specification clearly teaches that increasing the number of functional receptors may be accomplished by increasing the total number of receptor proteins on the surface of the cell or by replacing non-functional receptor protein with functional receptor protein and that the term "potentiate" is defined as any enhancement of the effects of the effector ligand (see page 1, lines 24-28). Thus, the instant claims encompass the teachings of Lufalla et al., and therefore the rejection is maintained for the reasons of record.